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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,559	11/27/2000	Wolf-Georg Forssmann	P65315US0	8027

136 7590 11/24/2003

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.**	**Applicant(s)**	
	09/509,559	FORSSMANN ET AL.	
	Examiner	**Art Unit**	
	Regina M. DeBerry	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10/02/2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *03 November 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☒ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *19-29*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 2. NOTE: Applicant has cancelled pending claims 19-29 and added claims 30-38. Newly submitted claim 35 now recites use of the purified peptide claim 30 comprising administering the purified peptide to "maintain" or promote bone growth in a person suffering from a degenerative or metabolic disease of the bone. The specification as originally filed, does not provide support for the limitation "maintain bone growth". Furthermore, this limitation would require further consideration/search of the prior art and possibly raise new enablement issues. In addition, newly submitted claim 37 now recites a method comprising administering the peptide according to claim 30 to a person in need thereof to "protect" or promote "bone density". The specification as originally filed, does not provide support for the limitation "protect bone density". Applicant cites page 1, lines 1-13 of the present specification, however, the exact wording or connotation of the instant claim is not readily apparent from said section. This limitation would require further consideration/search of the prior art and possibly raise new enablement issues

Continuation of 3. Applicant's reply has overcome the following rejection(s): If the amendment was entered, the rejection of claims 19, 20, 28 and 29 under 35 U.S.C. 102(e) as being anticipated by Takeshita et al., US Patent No. 5,869,638 as set forth at pages 3-5 of the previous Office Action (02 May 2003) would be withdrawn in view of the cancelled claims and in view of newly submitted claim 30 which now recites "consisting" (closed language).

If the amendment was entered, the rejection of claim 26 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, as set forth at page 6 of the previous Office Action (02 May 2003) would be withdrawn, in view of the cancelled claims.

If the amendment was entered, the rejection of claims 19, 23, 26. 28 and 29 under 35 U S.C 112, second paragraph, as set forth at pages 7-8 of the previous Office Action (02 May 2003) would be withdrawn, in view of the cancelled claims.

Continuation of 5. does NOT place the application in condition for allowance because: If the amendment was entered, newly submitted claims 35-37 would be rejected under 112, first paragraph, scope of enablement. Claim 35 recites, "use of the purified peptide claim 30 comprising administering the purified peptide to maintain or promote bone growth in a person suffering from a degenerative or metabolic disease of the bones". Claim 37 recites, "a method comprising admnistering the peptide according to claim 30 to a person in need thereof to protect or promote bone density". The instant claims are enabled for promoting bone growth or promoting bone density, but are not enabled for maintaining bone growth or protecting bone density.

Applicant states (Remarks/Arguments, page 7) that none of the present replacement, method claims 31 and 35-37 requires preventing or stopping [i.e., prophylaxis of] a degenerativie or metabolic bone disease, which enablement is allegedly lacking according to the statement of rejection. Applicant's arguments have been considered but are not found persuasive because claim 37 now recites protection of bone density. The limitation "protection" reads on preventing, stopping, i.e. prophylaxis of bone density. The instant specification does not teach protection of bone density. Furthermore, this limitation adds new matter.

Applicant states (Remarks/Arguments, page 8) that what is more, the statement of rejection, explicitly, finds that the instant specification is enabling for present claim 35, (which replaces claim 24, is a method of use, the use "comprising administering the protein [SEQ D NO:10] to maintain or promote bone growth in a person suffering from a degenerative or metabolic disease of the bones, and, in accordance with the statement of rejection as contained in the Office Action mailed October 10, 2002 (which is incorporated, by reference, into the current, Final Offiice Action). Applicant's arguments have been considered but are not found persuasive because the Examiner stated in the Office Action mailed October 10, 2002, that the specification was enabling for a method of administering CDGF consisting of SEQ ID NO:10 to "promote bone growth" NOT "maintaining bone growth". Furthermore, this limitation adds new matter.

The evidence as a whole indicates that the scope of enablement rejection should be maintained.

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